DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 20, 2015

Fujifilm Medical Systems, U.S.A., Inc.
Mary Moore
Senior Director, Regulatory Affairs
and Quality Assurance, Endoscopy
10 High Point Drive
Wayne, NJ 07470

Re: K143556
Trade/Device Name: Fujifilm Double Balloon Endoscopes Models EN-530T and EN-580T
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDA, FDF
Dated: July 13, 2015
Received: July 13, 2015

Dear Mary Moore,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143556

Device Name
Fujifilm Double Balloon Endoscopes Models EN-530T and EN-580T

Indications for Use *(Describe)*
The Fujifilm Double Balloon Endoscopes are intended for the visualization of the upper and lower digestive tracts. Specifically, for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, duodenum, small intestine, large intestine, and rectum.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Fujifilm Double Balloon Endoscope Models EN-530T and EN-580T

Date: December 15, 2014

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.,
Endoscopy Division
10 High Point Drive
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FDA Establishment Registration Number: 2431293

Contact Person:

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Identification of the Subject Device:

Proprietary/Trade Name:	Fujifilm Double Balloon Endoscopes, Models EN-530T and EN-580T
Common Name:	Enteroscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification

Enteroscope and accessories, 21 CFR § 876.1500,
Product Codes: FDA, FDF

Predicate Devices

- Fujinon, Inc., Double Balloon Enteroscope, Model EN-450P5/20 (K040048)
- Fujinon, Inc., Double Balloon Enteroscope, Model EC-450BI5 (K090116)

Intended Use / Indications for Use

The Fujifilm Double Balloon Endoscopes, Models EN-530T and EN-580T are intended for the visualization of the upper and lower digestive tracts. Specifically, for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, duodenum, small intestine, large intestine, and rectum.

Device Description

The Fujifilm Double Balloon Endoscopes, Models EN-530T and EN-580T and related accessories consist of double balloon endoscopes (models EN-530T and EN-580T), a hood (model DH-17EN), a balloon (model BS-2), an over-tube (model TS-13140), and a balloon controller (model PB-20).

The endoscopes are comprised of three general sections: an operation section, an insertion portion and an umbilicus. The operation section controls the angulation (up/down/left/right) of the distal end of the endoscope. The insertion portion contains glass fiber bundles, several channels and a charged couple device (CCD) image sensor. The glass fiber bundles allow light to travel through the endoscope and emit light from the tip of the insertion portion to illuminate the gastrointestinal cavity. This provides adequate light to the CCD image sensor to capture an image and display it on the monitor. The endoscope also contains several channels such as an air/water channel, a suction channel, a balloon channel and a forceps channel. The balloon controller is used to inflate or deflate the balloons on the distal end of the endoscope and on the over-tube through the balloon channel. The forceps channel is used to introduce endoscope accessories such as biopsy forceps for endoscopic procedures. The umbilicus section consists of electronic components needed to operate the endoscope when plugged to the video processor and the light source. The subject models are used in combination with Fujifilm's video processor, light source and peripheral devices (water tank, endoscope accessories, monitor, printer, DVD recorder, electrosurgical instruments, foot switch, and cart). The hood is an optional accessory that is attached to the distal end of the endoscopes and is intended to maintain the field of view during the endoscopic procedure.

The minor modifications to the endoscopes were made for the purpose of overall product enhancement and general technological advancement.

Technological Characteristics

A comparison of the technological characteristics between the subject and predicate devices is provided in the table below.

DESCRIPTION	EN-450P5/20 (K040048)	EC-450BI5 (K090116)	EN-580T	EN-530T
Indications for Use	The device is intended for the Optical visualization of the upper gastrointestinal tract. This includes the esophagus, stomach, duodenum, and small bowel. It is intended for the observation, diagnosis, and endoscopic treatment.	The device is intended for the optical visualization of the gastrointestinal tract. This includes the rectum, large and small intestines. It is intended for observation, diagnosis, and endoscopic treatment.	This device is intended for the visualization of the upper and lower digestive tracts. Specifically, for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, duodenum, small intestine, large intestine and rectum.	
Insertion route	Per oral	Trans anal	Per oral or trans anal	Per oral or Trans anal
CCD Type	1/6"	1/6"	1/9.7" double pixel	1/9.7"
Field of view	120 degrees	140 degrees	140 degrees	140 degrees
Resolution	0.09mm pitch chart is recognizable. (Distance:5mm)	0.07mm pitch chart is recognizable. (Distance:4mm)	0.056mm pitch chart is recognizable. (Distance:4mm)	0.063mm pitch chart is recognizable. (Distance:4mm)

DESCRIPTION	EN-450P5/20 (K040048)	EC-450BI5 (K090116)	EN-580T	EN-530T
	1.6mm pitch chart is recognizable. (Distance:100mm)	1.25mm pitch chart is recognizable. (Distance:100mm)	1.6mm pitch chart is recognizable. (Distance:100mm)	1.4mm pitch chart is recognizable. (Distance:100mm)
F number	6.21	7.05	7.2	7.2
Distal end diameter	8.5mm	9.4mm	9.4mm	9.4mm
Flexible portion diameter	8.5mm	9.3mm	9.3mm	9.3mm
Maximum diameter of insertion portion	9.0mm	10mm	10mm	10mm
Number of Light guide fiber	900x2	1200x2	650x2	650x2
Forceps channel diameter	2.2mm	2.8mm	3.2mm	3.2mm
Forceps channel length	2100mm	1620mm	2100mm	2100mm
Working length	2000mm	1520mm	2000mm	2000mm
Total length	2300mm	1820mm	2300mm	2300mm
Processor	VP-4400, VP-4400HD, VP-4440HD	VP-4400, VP-4400HD, VP-4440HD	VP-4440HD	VP-4400, VP-4400HD, VP-4440HD
LG Connector	400 series connector	400 series connector	500 series connector	500 series connector
Video Connector	400 series connector	400 series connector	500 series connector	500 series connector
Location of Balloon inlet	On the control portion	On the control portion	On the LG connector	On the LG connector

DESCRIPTION	PB-10 (K040048)	PB-20
Compatible endoscope	EN-450P5/20	EC-450BI5, EN-450P5/20, EN-450T5, EN-530T, EN-580T
Compatible overtube	TS-12140	TS-12140,TS-13140,TS-13101
Compatible Balloon	BS-1	BS-2
Power supply	120V 60Hz	120V 60Hz
Current consumption	0.37A	0.58A
Dimensions	W300 x H200 X D300 mm	W350 x H130 X D420 mm
Weight	8.7kg	10kg
Set air supply pressure	5.6kPa	5.6kPa
Warning pressure	8.2kPa	8.2kPa
Tubing	TY-01 and TY-02	TY-06D for use with EN-530T and EN-580T TY-04D for use with 400 Series
Trap for preventing fluid to invade the pump	Trap bottle (TP-01)	Membrane filter (for TY-06D, TY-04D)

DESCRIPTION	PB-10 (K040048)	PB-20
Foot switch terminal to connect the optional foot switch FS1.	No	Yes
The Video output terminal to the external monitor to graphically show the balloon conditions.	No	Yes

DESCRIPTION		DH-14EN (K040048)	DH-17EN
Outer diameter		10.8mm	11.5mm
Maximum diameter of attaching endoscope		12.5mm	13.5mm
Total length		8.0mm	8.0mm
Distance from the tip		1.5mm	1.5mm
Inner diameter of attaching portion		8.8mm	9.5mm
Inner diameter of distal end		7.8mm	8.5mm
Sterility		Non Sterilized	Non Sterilized
Reuse or single use		Single Use	Single Use
Material	Distal portion	EPDM JSR EP21	Silicone rubber TSE260-5U
	Attaching portion		

The subject devices are also used with the company's previously cleared balloon model BS-2 (K090116).

Substantial Equivalence

The subject and predicate endoscopes have the same intended use/indications for use of visualization of the digestive tracts. Per oral and trans anal insertion routes were already cleared in the company's predicate devices K040048 and K090116, respectively. They also have similar technological characteristics as shown in the table above. Both use the Double Balloon Endoscope system to access the gastrointestinal tracts. Device dimensions and visualization technology are also similar. The technological differences between the subject endoscopes and the predicate devices raise no new questions of safety or effectiveness. Bench testing data demonstrated that the subject endoscopes have substantially equivalent performance to the predicates.

Performance Data

EMC and electrical safety of the subject devices were evaluated using the following consensus standards: ANSI/AAMI ES60601-1:2005; IEC 60601-1-2:2007; IEC 60601-1-6:2010; and IEC 60601-2-18:2009.

Biocompatibility of the subject devices was evaluated using the following consensus standards: ISO 10993-1:2009; ISO 10993-5:2009; and ISO 10993-10:2010.

Cleaning, disinfection, and sterilization were evaluated according to the following consensus standards: AAMI TIR30:2011; AAMI TIR12:2010; AAMI/ANSI/ISO 11135-1:2007; and AAMI/ANSI/ISO 17665-1:2006.

Endoscope specific testing was conducted using the following consensus standards: ISO 8600-1:2013; ISO 8600-3:1997; and ISO 8600-4:1997.

Subject devices met performance specifications of the following additional testing:

- Time for inflation
- Operating pressure
- Frictional resistance
- Field of view
- Bending capability
- Rate of air supply
- Rate of water supply
- Rate of suction
- Viewing direction
- Resolution
- Pump air feed pressure
- Pump air evacuation pressure
- Pump air flow rate

Conclusions

The subject devices are substantially equivalent to the predicates based on intended use/indications for use and technological characteristics. The minor technological differences between the propose endoscopes and its predicate devices raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject endoscopes have substantially equivalent performance to the predicates.